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EXAMINER

ROSE, SHEP K

ART UNIT PAPER NUMBER

1614

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019408

Applicant(s)

ISHI BASHI DCA

Examiner

SILVER ROSE

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 05/15/2003
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 2, 3, 4 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2, 3, 4 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

There have been filed no terminal disclaimers and so remains the issue and ground of obviousness-type double patenting of these claims, over the claims of copending application 10/109, 868 and U.S. 6231343 taken in view of prior art describing (A) (B) (C) (D) as old, (as noted below), including Rylels et al (newly cited by applicants).

The composition claims, claims 1 to 8, 11 to 16, 19, 21 to 23, 25 to 30 have a preamble statement of intended use as "tooth bleaching" compositions, which preamble statement does not, in the USPTO, impart patentable novelty over any prior art compositions comprising (A) hydrogen peroxide or peroxide generating peroxy compound, (whether or not described for tooth bleaching), (B) titanium dioxide (whether or not described for initiating photocatalytic action with light irradiation), in an amount of 0.001 to 10%, as newly recited in claim 1 (as amended), (C) 1% to 5% (as newly recited in claim 1) any thickening agent (which will inherently impart viscosities in the range of 1,000 to 100,000 centipose (as newly recited in claim 1, as amended, and (D) water.

Applicants' counsel's arguments are convincing that there is no patentable distinction whatsoever in the selection of any encompassed species of thickening agent, whether recited in depending claims, or not, and they are regarded as obvious variants of each other. The declaration doesn't establish criticality in the selection of hectorite or saporite species of thickening agent, which are not the only claim encompassed and/or claim-recited thickeners, even if they are the elected species.

Additionally, the Australian patent office, on 28 April 2003 rejected counterpart Australian patent claims on Ryles et al, U.S. 5902568 describing compositions

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comprising (A) (B) (C) (D) noting that "initiating photocatalytic action with light irradiation" merely describes an activity of (B) titanium dioxide.

The Australian patent office found the composition claims lack novelty.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 to 8, 11 to 16, 19, 21 to 23, 25, 26 are rejected under 35 U.S.C. 102(A/B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ryles et al U.S. 5902568, (newly cited by applicants) who describe (B) titanium dioxide, kept apart in a bicarbonate paste, from the (A) peroxide gel, both in (D) aqueous vehicles, with (C) thickening agents (column 4, lines 18 to 24): any natural or synthetic thickening agent, (0.1 to 10%,) including: hydroxypropyl methyl cellulose, hydroxyethyl cellulose, sodium carboxymethylcellulose xanthon gum, trayaconth gum, karaya gum, Arabic gum, Irish Moss, starch, alginates and the composition claims

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reciting other known natural or synthetic thickening agents would be "immediately envisioned" obvious to select species, In re Schauman et al 197 USPQ 5, Carrageenan. The declaration was not submitted to establish that 0.1 to 10% of these (non-clay) thickening agents are not apt species for applicants' purposes, even if encompassed by claims 1 to 4, 8 to 12, 21 to 30, and even if hectorite and saponite are apt species of thickening agents, evaluated by ^{Declarant} ~~Relevant~~.

The Australian patent office found Au-A-90956/98 (equiv of JP. 11-92351 and Ishibashi et al U.S. 6231343 and PCT WO 99/15143) to disclose the same actives for toothbleaching ^{with} ~~will~~ the same improved tooth bleaching problem to be solved, with a thickener, lacking ^{any} ~~only~~ inventive step; this is the basis for the obviousness-type ground of double patenting herein.

The Australian patent office action made of record by applicants is not inconsistent with the USPTO prosecution herein, (once the election of species of thickening agents is hereby withdrawn, as they are not "patentably distincted" species (in view of counsel's remarks).

Applicants' May 15 2003 amendments and arguments of applicants' counsel herein, have been carefully considered, but are not persuasive of reversible error or of patentability of any claims as presently amended. Applicants' counsel herein was initially requested to furnish the USPTO examiner with copies of application 10/109,868 (Eguachi et al U.S. 2002/0177091) to investigate the issue of obviousness-type double patenting on but ^{he refused} be revised. They were obtained from co-applicant Ishibashi et al's U.S.

counsel who informed the U.S. PTO examiner that it was a published patent application, U.S. 2002/0177091.

When the May 15 2003 amendment was received, the USPTO examiner immediately left a voicemail message ^{with} William Solomon, applicant's counsel herein, that terminal disclaimers, if filed, could overcome the method claims, (but not the composition claims) however, no response was received to this attempt to advance the prosecution.

This application, Serial No. 10/019,408 filed December 28, 2001 by Tokuro Ishibashi et al, is a 371 of PCT/JP00/04397 with an International Filing Date of July 3, 2000 based on (untranslated) Japanese priority documents filed July 2, 1999.

Page 6, lines 13 to 21 sets forth as background information the admitted prior art fact that in Japanese Patent Application laid Open No. H 11-92351/1999 that "the inventors of the present invention" (Ishibashi et al) had previously disclosed that the combined use of (A) titanium dioxide having photocatalytic action and (B) low concentration aqueous solution of hydrogen peroxide, as efficacious constituent, achieved the intended objective. It was published 6 April 1999, and seems to be a counterpart of Ishibashi et al (I), U.S. 6,231,343 (5/01), which was PCT Published April 1, 1999, Ishibashi et al (II) PCT WO 99/15143, both clearly disclosing and teaching that (C) any inorganic or organic gel forming a solution or paste of (A) and (B) can be applied to the dental teeth surfaces and irradiated with light (See (I) col. 5 lines 53-68) col. 6, lines 45-47) with UV ray irradiation of a wave length of 380 nm or less (col. 7, lines 23 to 37, or visible blue or LED violet light, claims 1 to 16.

Claims 1 to 16 (method claims 1 to 7, 11 to 13 composition and system claims 8 to 10, 14 to 16) of Ishibashi et al (I) U.S. 6,231,343 are seen to raise an issue of obviousness-type double patenting (overlap in scope) for the amended claims presented herein. The method claims in (I) apply (A) and (B) onto discolored teeth and irradiate with light.

Copending claim 1 of (co-applicant Takuro Ishibashi) U.S. Published Patent application 10/109,868, filed April 1, 2002 (U.S. Patent Pub. 2002/0177097 Published November 28, 2002), after relating the same admitted prior art background information facts, at page 1, paragraphs 14 and 15 claims (claim 1) a system for bleaching discolored teeth, (same as herein) wherein (A) titanium dioxide and (B) hydrogen peroxide are applied to the surface of the teeth and are irradiated with 380 to 420 nm wavelength light, (See also: Page 2, paragraphs 20, 33, 38, 42, page 3 paragraphs 43, 44, 45, Table I page 4, page 5, paragraphs 73, 74, 75, 81, 82, 83, 88, 89, 90, 95, 96, 97, 103, 108), and, accordingly, claim 1 therein is seen to raise issue of obviousness-type double patenting of method claims 9, 10, 17, 18, 20 and 24 wherein the same (A) and (B) is applied to the surface of a discolored tooth and irradiated with light, which light only in dependent claims 10 and 18 , has a wave length of 300 nm or longer, (overlap in scope).

Herein, in addition to the method claims 9, 10, 17, 18, 20 and 24 (as noted above) which recite a step of light irradiation of (A) and (B) after the (A) and (B) tooth bleaching composition applied onto the surface of a discolored tooth, there are also

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composition claims 1 to 8, 11 to 16, 19, 21 to 23, 25 and 26 to (A) and (B) and (C) thickening agent, said (C) Thickening agent being not necessarily of a clay (claims 6, 14) but also of phosphoric acid (claims 5, 13) or of a phosphate, like tetrasodium pyrophosphate (claims 5, 15).

These composition claims of (A) (B) and (C), (as noted above) are stated in their preamble to be tooth bleaching compositions, and the (B) need not be hydrogen peroxide (claims 4, 12) the most comprehensive species constructively elected, it can be one of a Markush group of hydrogen peroxide generating compounds (claims 3, 11).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9, 10, 17, 18, 20 and 24 stand/or are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 16 of U.S. Patent No. 6,231,343. Although the conflicting claims are not identical, they are not patentably distinct from each other because overlap in scope to the same method.

Claims 9, 10, 17, 18, 20 stand/or are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 16 of U.S. Patent No. 6,231,343 in view of prior art describing encompassed species of thickening agents as apt for the claimed composition of the method, namely:

Mori et al, pyrophosphoric acid, salts, titanium dioxide U/V irradiated at less than 400 nm wavelengths;

Dobrozsi, carbamide peroxide and tetrasodium pyrophosphate oral care agent with .2-50% clay.

Nakamara et al, photocatalytic titanium dioxide and hydrogen peroxide paint for ceramic surfaces :

Smigel (III) 1.0 to 15% of « V-GUM » a magnesium aluminum silicate (clay) thickening agent for 0.5 – 5% of six encompassed peroxide species generating hydrogen peroxide, with 0.1-10% titanium dioxide.

Wagner (II) phosphoric acid sodium phosphates tetrasodium pyrophosphate, excipients for hydrogen carbomide or urea peroxide, photocatalalyzed by titanium dioxide.

Claims 9, 10, 17, 18, 20 and 24 stand/or are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/109.868 – US 2002/0177091. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope to the same invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 9, 10, 17, 18, 20 and 24 stand/or are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/109,868 – US 2002/0177091 in view of Wagner (II) Smigel (III) Mori et al Dobrozsi and Nakamara et al (details as noted above), prior art describing encompassed species of thickening agents as apt for the claimed compositions of the method.

This is a provisional obviousness-type double patenting rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 to 8, 11 to 16, 19, 21 to 23, 25 and 26 stand/or are rejected under 35 U.S.C. 102((A)(B)) as being anticipated by each of: Ishibashi et al, (B/N on PTO-892) (I-II) PCT Published 4-1-99 describing the same titanium dioxide and hydrogen peroxide can be formulated with any inorganic gel or organic gel carrier (which is a synonym of “thickening agent”), the clays being immediately envisioned inorganic gel forming agents, gelling agent and thickening agents being synonymous, In re Schauman et al 197 USPQ 5 and immediately envisioned, as well as each of:

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Dobrozsi, Wagner (I-II) and Smigel (I-II-III) each describing compositions of an encompassed species of a peroxide, and a claim-encompassed species of a thickening agent, in encompassed percentage concentration of each:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 to 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishibashi, JP 1,192,351 (6 April 1999 taken with Cornell/Dametron U.S. 5032178 Lion Corp JP 60-75413 and Ryan JP 51-59097 for the reasons stated in the PCT /JP00/04397 International Preliminary Examination Report.

2. Citations and explanations

Document 1: JP, 11-92351, A (Takuro Ishibashi) 6 April 1999 (06.04.99)

Document 2: U.S. 5032178, A (Demetron Research Corporation) 16 July 1991 (16.07.91)

Document 3: JP, 60-75413, A (Lion Corp.) 27 April 1985 (27.04.85)

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Document 4 : Jp, 51-59097, A (John William Ryan) 22 May 1976 (22.05.76)

Claims 1-6 and 8-10

Document 1 Ishibashi et al JP 1192351 6 April 1999 describes a tooth bleaching composition containing a paste of anatase-type titanium dioxide and hydrogen peroxide at a concentration of 35% or less, and it describes a method for bleaching teeth in which this composition is applied to the teeth and irradiated with light having a wavelength of 250-600nm.

Document 2 Cornell U.S. 5032178 describes including a thickening agent to form a gel or paste in a teeth bleaching composition so that a bleaching solution containing hydrogen peroxide that can easily drip from the surface of the teeth will adhere to the surface of the teeth without dripping. The thickening agents are silica gelling agent (col. 3, lines 59-66) as well as cellulose ether thickeners (col. 4, lines 42 to 68, (or Gantrez polymer) light at 400 to 700nm See: column 4, lines 8 to 20 claim 4.

Therefore, it is obvious to persons skilled in the art to add the thickening agent described in document to the teeth bleaching composition described in document 1 to prevent it from dripping from the surface of the teeth. Furthermore, optimizing the content of hydrogen peroxide and the wavelength of irradiating light are matters that are obvious to persons skilled in the art.

Therefore, the inventions set forth in Claims 1-6 and 8-10 do not appear to involve an inventive step.

Claims 5, 6, and 8-10

Documents 3 and 4 describe adding montmorillonite and hectorite as a thickening agent to compositions for use in the mouth.

Therefore, adding the montmorillonite and hectorite described in documents 3 and 4 as a thickening agent in the same kind of composition for use in the mouth instead of the thickening agent described in document 2 is an obvious matter to person skilled in the art.

Therefore, the inventions set forth in Claims 5, 6 and 8-10 do not involve an invention step.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP.

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609.

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The examiner can normally be reached on Monday, Tuesday and Thursday from 7:30 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



**SHEP K. ROSE
PRIMARY EXAMINER**

Rose/tgd
July 21, 2003